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Division of Dockets Management  
Food and Drug Administration  
Room 1061 (HFA - 305)  
5630 Fishers Lane  
Rockville, MD 20852

**RE: Docket 2004P-0223/CP 1**

To Whom It May Concern:

Campbell Soup Company submits these comments in response to the Citizen's Petition filed by General Mills on May 11, 2004, which has proposed that the FDA initiate rulemaking to define and implement definitions for "Excellent Source," "Good Source," and "Made With" claims relating to whole grain content in foods.

The whole grain descriptors proposed in the Citizen's Petition, are as follows:

Excellent source of whole grain: the terms "excellent," "rich in," or "high in" whole grain(s) may be used on the label and in labeling of foods provided that the food contains 16g or more of whole grain per labeled serving.

Good source of whole grain: The terms "good source," "contains," or "provides" whole grain(s) may be used . . . provided that the food contains 8g to 15g of whole grain per labeled serving.

Made with whole grain: The term "made with" whole grain(s) may be used . . . provided that the food contains at least 8g of whole grain per labeled serving.

For the reasons elaborated below, Campbell Soup Company disagrees with these proposed definitions. In fact, we believe that nutrient content claims for whole grain are simply not the best vehicle for educating consumers about whole grains. For the reasons stated below, we believe that issuance of a guidance document supporting declarations of quantity for whole grains based upon serving definitions elaborated in USDA's MyPyramid, would better educate and guide the public to consume whole grains. If the petition submitted by General Mills were accepted, consumers would be exposed to claims based on units different from USDA's MyPyramid. This will undermine FDA and USDA's educational efforts behind the 2005 Dietary Guidelines and the MyPyramid programs.

Definitions of "Excellent Source" and "Good Source"

We fully support well-considered efforts to encourage the consumption of whole grains, and applaud FDA's and USDA's efforts to do so. The recent 2005 Dietary Guidelines for

2004P-0223

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Americans and the USDA's MyPyramid both emphasize the importance of whole grain consumption. The FDA itself has recently reaffirmed the significance of whole grain products in diets by accepting Frito-Lay Inc.'s notification for a health claim based on an authoritative statement issued by the NAS Committee on Diet and Health. The notified health claim states:

“Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease.”

This is the third health claim allowed by FDA for whole grains under FDAMA. See also FDA approved health claims in 21 CFR 101.76 relating to diets low in fat and high in fiber-containing grain products, fruits and vegetables, and cancer risk, and 21 CFR 101.77 relating to diets low in saturated fat and cholesterol and high in fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease. The FDA could help educate the public about the importance of whole grains by issuing a guidance document, rather than regulations, building upon the new MyPyramid's concept of ounce equivalents of whole grain.

Companies should be encouraged to express the whole grain content of their products in such units. Specifically, if, as elaborated in the MyPyramid document, the food is classified as a grain food form (*e.g.*, bread, crackers, English muffins), and 100 percent of the grain in the food is whole grain, then each one ounce portion of the food can claim that it delivers a one ounce equivalent serving of whole grains. Similarly, if a food is classified as a grain food form and contains less than 100 percent of the grain as whole grain, the number of whole grain servings can be determined by multiplying the fraction of whole grain over total grain by serving size, divided by one ounce. Thus, for example, for a hypothetical 50g labeled serving of a bagel formulated with 70 percent of whole grain flour and 30 percent refined flour, the equivalent serving of whole grain would be determined by the following calculation:  $(50/28.4) \times 70/100 = 1.23$  ounce equivalent serving of whole grain. As a third example, if a food is a combination of non-grain food and grain food containing a whole grain ingredient, *e.g.*, soup containing whole grain rice, the ounce equivalent of whole grain would be determined by the previous calculation multiplied by the fraction of the combination food that is a whole grain food. As with any other product information, any on-label discussion of whole grain content would have to avoid being misleading.

We do not believe that consumers would clearly benefit from “source” definitions for whole grains. They would be exposed to claims based on units different from those used in MyPyramid. If the petition submitted by General Mills were accepted, consumers would likely be confused, and the FDA's and USDA's educational efforts behind the 2005 Dietary Guidelines and the MyPyramid program would likely be undermined.

Should the FDA wish to move forward with regulations to define “Excellent Source” and “Good Source” of whole grains, then it should apply its customary 20 percent and 10

percent factors to the Food Guide's daily recommended minimum. For example on a 2000 Kcal diet, the daily whole grain intake recommendation is three ounce equivalent servings of whole grains per day. This would translate to a requirement that a food designated as an "Excellent Source" of whole grain provide at least 0.6ounce equivalent serving of whole grain, and a food designated as a "Good Source" of whole grain provide a minimum of 0.3ounce equivalent serving of whole grain. The 16g and 8g numbers proposed in the Citizen's Petition do not properly translate to the Dietary Guidelines' recommendations and, in fact, are unnecessarily high. In fact, they would preclude, or severely limit, grain content statements, especially "Excellent Source" claims, for the most commonly consumed whole grain products—breads and rolls—and could thereby have the effect of discouraging, rather than encouraging, whole grain consumption.

#### "Made With" Whole Grain

Regardless of whether and how the FDA chooses to define "Excellent Source" and "Good Source" claims for whole grains, the Citizen's Petition's proposal to require 8g of whole grains per labeled serving to support a claim of "Made With" whole grains is unnecessarily restrictive. The Petition contains no reasoned support for the proposal, other than it is the same requirement as for a "Good Source" claim. Use of the term "Made With" on a label should be permitted so long as it does not cause a product to be misbranded, that is, such a claim should be truthful, not misleading and include, if necessary, any additional information necessary to make a statement not misleading. (See 21 USC §201 (n)). As with any other similar claim of "Made With" for a non-nutrient, the FDA has ample authority and expertise to determine whether such a claim is misleading as used. To confine "Made With" claims to an arbitrarily high level would deprive the consumer of useful information and potentially discourage the consumption of incrementally beneficial foods containing whole grain.

#### CONCLUSION:

For the reasons stated, the FDA should reject the proposal by General Mills to define source and "made with" claims for whole grains. The definitions are inconsistent with the recently issued 2005 Dietary Guidelines, and the MyPyramid document, and are unwarranted. Indeed, by defining terms based on arbitrarily high levels, the proposal would discourage the consumption of a number of vital whole grain products, including many breads and rolls. Consumers would be better served by the issuance of a guidance document that would be consistent with, and support, the educational efforts behind the Dietary Guidelines and the MyPyramid publication.

Sincerely,



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